



U.S. Department
of Transportation

**Pipeline and
Hazardous Materials
Safety Administration**

Office of the
Chief Counsel

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***Hazardous Materials Safety
Law Division***

NOTICE OF PROBABLE VIOLATION

PHMSA Case No. 05-0254-SB-EA

Date Issued:

DEC 22 2005

Docket No.: PHMSA-2005-23452-1

Respondent: Alden Medical Center, LLC
360 Cold Spring Avenue
West Springfield, MA 01089
Attn: Mr. Damon D'Amico, General Manager

No. of Alleged Violations: 4

Maximum Possible Assessment: \$130,000

Total Proposed Assessment: \$5,125 (Includes a \$1,375 reduction for corrective action)

The Office of the Chief Counsel of the Pipeline and Hazardous Materials Safety Administration (PHMSA) alleges that you (the Respondent named above) violated certain provisions of the Federal Hazardous Materials Transportation Law, 49 U.S.C. § 5101 *et seq.*, and/or the Hazardous Materials Regulations (HMR), 49 C.F.R. Parts 171 - 180. PHMSA sets forth the specific allegations in Addendum A to this Notice.

What is the maximum and minimum civil penalty that PHMSA can assess? Federal law sets a civil penalty of not more than \$32,500 and a civil penalty of not less than \$275 for each violation of the Federal Hazardous Materials Transportation Law or the HMR committed after October 1, 2003, and no more than \$27,500 and no less than \$250 for each violation occurring before October 1, 2003 but after January 21, 1997 (49 C.F.R. §107.329(a)). Each day of a continuing violation constitutes a separate violation for which the maximum penalty may be imposed (49 U.S.C. § 5123(a)(2)).

What factors does PHMSA consider when proposing and assessing a civil penalty? Federal law requires PHMSA to consider certain factors when proposing and assessing a civil penalty for a violation of Federal Hazardous Materials Transportation Law or the HMR. Please refer to Addendum B to this Notice for more information concerning these factors.

When is my response due? You must respond within thirty (30) days from the date that you receive the Notice (49 C.F.R. § 107.313(a)). **PHMSA encourages you to submit your response by e-mail or fax** when possible. PHMSA may extend the 30-day period for your response if you ask for an extension, and show good cause, within the original 30-day period (49 C.F.R. §107.313(c)). Please contact the undersigned attorney if you have any questions.

What are my response options? You may respond to this Notice in any of three ways:

- (1) Admit the alleged violations and pay the proposed assessment (49 C.F.R. § 107.313(a)(1));
- (2) Send an informal response, which can include a request for an informal conference (49 C.F.R. § 107.313(a)(2)); or
- (3) Request a formal hearing (49 C.F.R. § 107.313(a)(3)).

PHMSA provides information on these options in Addendum B to this Notice and the Office of the Chief Counsel's homepage (<http://rspa-atty.dot.gov>). PHMSA explains its procedures for assessing civil penalties and imposing compliance orders in 49 C.F.R. § 107.307 through 107.331.

What happens if I fail to respond? You waive your right to contest the allegations made in Addendum A to this Notice if you fail to respond within thirty (30) days of receiving it (or by the end of any extension). Also, the Chief Counsel may make a finding of fact consistent with the allegations in this Notice and assess an appropriate civil penalty if you fail to respond within the applicable time frame.



Thomas D. Seymour, Attorney
Phone: (202) 366-6139
tom.seymour@dot.gov

Enclosures: Addendum A
Addendum B
Addendum C
Case Exhibits

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

PHMSA Case No. 05-0254-SB-EA

SPECIFIC ALLEGATIONS

Probable Violation No. 1

Respondent offered a hazardous material for transportation when Respondent failed to close the packaging in accordance with the manufacturer's closure instructions, in violation of 49 C.F.R. §§ 171.2(a), 173.22(a)(4) and 173.24(f)(2).

Factual Allegations/Averments

- A. On March 11, 2005, Respondent offered a hazardous material (hydrogen peroxide and peroxyacetic acid mixture, stabilized, 5.1 (8), UN 3149, PG II) for transportation in commerce.
 - B. On a date on or before March 11, 2005, Respondent prepared the hazardous materials packagings for transportation in commerce.
 - C. Respondent packaged the hazardous material in a combination packaging consisting of four (4) plastic inner bottles contained inside of a 4G fiberboard box that was marked UN4G/Y25.6/S/04/USA/+AX4497.
 - D. The outer packaging was subject to design qualification testing and UN certification using 2" or 3" wide poly tape to close the packaging.
 - E. Respondent offered the packagings for transportation and caused the packagings to be transported after Respondent used staples to close the outer packagings.
- Please see Inspection/Investigation Report Number 05421016 at page 2, and the exhibits that accompany this report, which are incorporated herein.

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Probable Violation No. 2

Respondent marked the outer packaging of a combination packaging inconsistent with the packaging's United Nations certification, in violation of 49 C.F.R. §§ 171.2(a) and (c), 178.503(a)(2) and Approval CA-00100008.

Factual Allegations/Averments

- A. On January 28, 2003, A third party laboratory tested a combination packaging for Respondent.

Probable Violation No. 2 - Continued

B. The third party lab:

- 1) Tested the packaging under Approval CA-0010008; and
- 2) Provided Respondent test report number 1584, which covered the testing and certification of Respondent's packaging.

C. The test reports certifies the packaging to and informs the person who uses this packaging to mark the packaging ""UN4GW/Y7/S/- -(last two digits of the year box manufactured)/USA/+AV1584"

D. Respondent marked the packagings "UN4G/Y5.7/S/04/USA/+AV1584."

- Please see Inspection/Investigation Report Number 05421016 at page 3, and the exhibits that accompany this report, which are incorporated herein.

Probable Violation No. 3

Respondent offers hazardous materials for transportation in quantities that require the transport vehicle to display a placard when Respondent developed a security plan but when Respondent failed to implement the security plan and to provide in-depth security training, in violation of 49 C.F.R. §§ 171.2(a), 172.202(a), (b) and (d) and 172.704(a)(5).

Factual Allegations/Averments

A. On March 11, 2005, Respondent offered 3,520 pounds of a hazardous material (hydrogen peroxide and peroxyacetic acid mixture, stabilized, 5.1 (8), UN 3149, PG II) for transportation in commerce.

B. On March 11, 2005, Respondent had a written security plan.

C. On March 11, 2005, Respondent had not implemented its security plan.

D. On March 11, 2005, Respondent had not provided the appropriate employees with in-depth security training.

- Please see Inspection/Investigation Report Number 05421016 at page 4, and the exhibits that accompany this report, which are incorporated herein.

Probable Violation No. 4

Respondent offers hazardous materials for transportation in quantities that require the transport vehicle to display a placard when Respondent failed to register with the United States Department of Transportation (DOT) as a person who offers hazardous materials for transportation in commerce, in violation of 49 C.F.R. §§ 107.601(a) and 107.171.2(a).

Factual Allegations/Averments

A. On March 11, 2005, Respondent offered 3,520 pounds of a hazardous material (hydrogen peroxide and peroxyacetic acid mixture, stabilized, 5.1 (8), UN 3149, PG II) for transportation in commerce.

B. On March 11, 2005, Respondent was not registered with DOT as a person who offers hazardous materials for transportation in commerce.

- Please see Inspection/Investigation Report Number 05421016 at page 5, and the exhibits that accompany this report, which are incorporated herein.

**FACTS ALREADY CONSIDERED (UNDER 49 C.F.R. § 107.331) IN SETTING
PROPOSED PENALTIES**

Prior Violations of the Hazardous Materials Regulations:

PHMSA increases proposed penalties when Respondent has committed a prior violation of the Federal Hazardous Materials Transportation Law or the HMR within the last six years, as determined through a civil penalty case, criminal case, or ticketing process (49 C.F.R. § 107.331(d)). More specifically, “the general standards for increasing a baseline proposed penalty on the basis of prior violations are . . . (1) for each prior civil or criminal enforcement case –25% increase over pre-mitigation recommended penalty, and (2) for each prior ticket–10% increase over pre-mitigation recommended penalty” (49 C.F.R. Part 107, Subpart D, Appendix A, Section IV, E).

PHMSA’s records do not contain any prior violations by Respondent, and no prior violations have been considered in determining the proposed assessment for the violation in this Notice.

Corrective Action:

An important purpose of PHMSA’s enforcement program is to bring the regulated community into compliance with the Hazardous Materials Regulations, and to promote ongoing efforts by that community to maintain compliance. In determining the final penalty assessment, PHMSA considers documented evidence of actions taken by a Respondent to correct violations and ensure that they do not recur (49 C.F.R. § 107.331 (g)).

In its March 29 and April 26 and 28, 2005 letters, Respondent described and documented its corrective action as follows:

Probable Violation No. 1 – Respondent stated that it will be using tape to close the packagings with all future production runs. However, Respondent did not address any actions that it had taken to rectify the current packagings that Respondent was using until the new production run. Based on this corrective action, PHMSA reduced the proposed civil penalty for this probable violation by \$375 (15%). Prior to receiving any further reduction of the proposed civil penalty for this probable violation, Respondent should provide documentation that demonstrates what actions it had taken relative to the packagings that it already had in stock.

Probable Violation No. 2 – Respondent provided documentation that shows that contain the proper markings and that Respondent will place over all the current packaging markings. Respondent has also ordered a new run of packagings that will marked in accordance with the required markings. Based on this corrective action, PHMSA reduced the proposed civil penalty for this probable violation by \$125 (25%).

Probable Violation No. 3 – Respondent provided documentation that shows that it has provided its employees with in-depth security training. Based on this corrective action, PHMSA reduced the proposed civil penalty for this probable violation by \$625 (25%).

Probable Violation No. 4 – Respondent has registered with the DOT. Based on this corrective action, PHMSA reduced the proposed civil penalty for this probable violation by \$250 (25%).

Financial Status

Under 49 C.F.R. §107.331 (e) and (f), the proposed penalty may be reduced if Respondent demonstrates that it is unable to pay that penalty, or if payment of the proposed penalty would affect Respondent's ability to continue in business. Respondent's poor financial condition may be a basis for reducing the proposed penalty; a healthy financial condition is *not* a basis for increasing the penalty.

PHMSA has no information that indicates that Respondent is unable to pay the proposed penalty. If Respondent believes it lacks the ability to pay the proposed penalty or that the proposed penalty will affect Respondent's ability to continue in business, Respondent should submit a current balance sheet (certified if possible) or other evidence of its assets and liabilities.

TOTAL CIVIL PENALTY PROPOSED

Probable Violation	Maximum Possible Penalty	Baseline Penalty	Increase for Priors	Corrective Action	Proposed Penalty
1	\$32,500	\$2,500	\$ 0	\$375	\$2,125
2	\$32,500	\$500	\$ 0	\$125	\$ 375
3	\$32,500	\$2,500	\$ 0	\$625	\$1,875
4	\$32,500	\$1,000	\$ 0	\$250	\$750
TOTAL	\$130,000	\$6,500	\$ 0	\$1,375	\$5,125

DEPARTMENT OF TRANSPORTATION
PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION

How do I respond to this Notice of Probable Violation (Notice)?

You may respond to this Notice in any of three ways:

- (1) Pay the proposed assessment (49 C.F.R. § 107.315);
- (2) Send an informal response, which can include a request for an informal conference (§ 107.317); or
- (3) Request a formal hearing (§ 107.319).

How do I pay the proposed assessment?

You pay the proposed assessment by:

- (1) Sending a wire transfer, through the Federal Reserve Communications System (Fedwire), to the U.S. Treasury account (49 C.F.R. § 89.21(b)(3). Addendum C contains the instructions for sending wire transfers. Questions concerning wire transfers should be directed to: Financial Operations Division (AMZ-300), ATTN: Shelley Willis, Federal Aviation Administration, Mike Monroney Aeronautical Center, P.O. Box 25082, Oklahoma City, OK 73125 (Telephone No. 405-954-8893).

Or

- (2) Sending a certified check or money order if the penalty amount is \$10,000 or less. The certified check or money order must be payable to the "U.S. Department of Transportation" and must be mailed to the Chief, Financial Operations Division, Attn: Shelley Willis, Federal Aviation Administration, Mike Monroney Aeronautical Center, AMZ-300, P.O. Box 25082, Oklahoma City, OK 73125.

Or

- (3) Using a credit card via the Internet. To pay electronically with a credit card, visit the following website address and follow the instructions:

<https://www.pay.gov/paygov/>

Where do I send my response?

You must address your informal response or formal hearing request to the attorney who issued the Notice at the following address:

Pipeline and Hazardous Materials Safety Administration
Office of the Chief Counsel (PHC-10)
Room 8417
U.S. Department of Transportation
400 Seventh Street, S.W.
Washington, D.C. 20590-0001

When is my response due? (§ 107.313)

You must respond to the Notice within thirty (30) days of the date you receive it. The attorney who issued the Notice may extend the 30-day period for your response if you ask for an extension, and show good cause, within the original 30-day period.

What happens if I do not respond? (§ 107.313)

If you fail to respond to the Notice within thirty (30) days of receiving it (or by the end of any extension), you will waive your right to contest the allegations made in Addendum A to the Notice. In addition, the Chief Counsel will issue a default Order finding the facts as alleged in the Notice and assessing the civil penalty as outlined within that notice.

May I propose a compromise offer? (§ 107.327)

Yes. At any time before an order is issued and referred to the Attorney General for collection, you may propose to compromise a civil penalty case by submitting a specific compromise offer amount to the attorney handling the case (§ 107.327). The Chief Counsel may also propose a compromise.

If a compromise is agreeable to all parties, the attorney handling the case will forward a compromise agreement to you for signature. This document will outline the terms of the joint agreement and you must return a signed original to the attorney handling the case within 30 days. After this agreement has been returned it will be signed by the assigned attorney and presented to the Chief Counsel with a request that the Chief Counsel adopt the terms of that agreement by issuing a Compromise Order (49 C.F.R. § 107.327(a)(1)). The terms of the agreement constitute an offer of compromise until accepted by the Chief Counsel. When you agree to a compromise, you give up your right to appeal the order issued by the Chief Counsel.

What should I include in my informal response? (107.317)

Your informal response must contain written explanations, information or arguments that respond to the allegation(s), the amount of the proposed civil penalty, or the terms of a compliance order. Provide complete documentation of your explanations and arguments. A specific format is required for an informal response.

May I request an informal conference? (107.317)

Yes. You may request an informal conference as part of your informal response. Please describe the issues you want to discuss during the conference. After receiving your request, the attorney handling the case will contact you to arrange the conference. Normally the conference will be held by telephone, and the attorney handling the case and the inspector who conducted the compliance inspection will participate in the conference.

What happens after I submit an informal response to the Notice?

We will hold an informal conference if you have asked for one. Based on the Notice, the evidence supporting the Notice, any written explanations, information and documentation that you provide, and matters presented at a conference, the Chief Counsel decides the case. The Chief Counsel may issue an order finding all or some of the violation(s) alleged in the Notice or may withdraw all or some of the alleged violation(s). If the Chief Counsel finds violation(s), the order will assess a civil penalty.

How do I appeal an order? (§ 107.325)

You may appeal an order to PHMSA's Administrator.

How do I request a formal hearing? (§ 107.319)

You must request a formal hearing within 30 days of the date that you receive the Notice. If you are granted an extension of time to respond to the Notice, you must submit a formal hearing request by the end of the extended time period. If you do not request a formal hearing within the specified time, you will waive your right to a formal hearing.

Your request for a formal administrative hearing must include the following:

- (1) The name and address of the respondent and any other person submitting the request;
- (2) A statement of which allegations of violations are not in dispute; and
- (3) A description of the issues that you will raise at the hearing. (The Administrative Law Judge will decide whether issues not raised in the request may be raised at the hearing.)

After receiving a request for a hearing that complies with these requirements, the Chief Counsel will request an Administrative Law Judge from the DOT Office of Hearings to preside over the hearing. Once an Administrative Law Judge is assigned, all further matters in the proceeding will be conducted by the Administrative Law Judge. Either you or PHMSA may appeal the decision of the Administrative Law Judge to PHMSA's Administrator.

How does PHMSA determine if I have committed a violation?

This is a civil penalty case and PHMSA uses the "knowingly" standard, which is defined in the Federal hazardous materials transportation law (See 49 U.S.C. 5123(a)(1)), in all civil penalty cases. The standard for a violation is similar to "negligence." After considering all the available information (including the additional information you provide in your response to the Notice), PHMSA must find either that (1) you had "actual knowledge" of the facts giving rise to the violation, or (2) you had "imputed knowledge," of the facts giving rise to the violation, in that a reasonable person acting in the circumstances and exercising reasonable care would have that knowledge. PHMSA does not need to find that you actually knew about, or intended to violate, requirements in the Federal hazardous material transportation law or the HMR.

What factors does PHMSA consider when proposing and assessing a civil penalty? (§ 107.331)

PHMSA considers the following factors when proposing and assessing a civil penalty for a violation of the regulations:

- (1) The nature and circumstances of the violation(s);
- (2) The extent and gravity of the violation(s);
- (3) The degree of your culpability;
- (4) Your history, if any, of prior offenses;
- (5) Your ability to pay the penalty;

- (6) The effect of the penalty on your ability to continue in business;
- (7) The size of your business, and
- (8) Other matters as justice may require.

The nature and the timeliness of any corrective action you take to prevent future violations similar nature will be considered under item No. 8. However, you must submit documented evidence of that corrective action to the PHMSA attorney. If you have submitted documented evidence regarding any of these factors during PHMSA's investigation of the alleged violation and that documentation is referenced in the Notice or accompanying Inspection/Investigation Report, you do not need to resubmit it.

Under the Small Business Regulatory Enforcement Fairness Act (SBREFA), PHMSA must consider the rights of small entities in enforcement actions. PHMSA's hazardous materials enforcement program has been designed to consider small businesses and the penalties that PHMSA proposes and assesses are generally considered appropriate for small businesses. PHMSA takes into consideration the size of the company when proposing and assessing a civil penalty.

However, special consideration may not be given to a small business if:

- (1) The small business has not corrected its violation(s) within a reasonable time;
- (2) The small business has committed one or more prior violations of the HMR;
- (3) The violations involve willful conduct;
- (4) The violations pose serious threats to health, safety or the environment; or
- (5) The small business has not made a good faith effort to comply with the law.

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. Our objective is to ensure a fair regulatory enforcement environment.

You have a right to contact the Small Business Administration's national Ombudsman at 1-888-REG-FAIR (1-888-734-3247) or www.sbs.gov/ombudsman regarding the fairness of the compliance and enforcement activities by this agency.

The Pipeline and Hazardous Materials Safety Administration strictly forbids retaliatory actions against its employees. As such, you should feel confident that you will not be penalized for expressing your concerns about compliance and enforcement activities.

Where can I find more information on how PHMSA handles hazardous materials enforcement cases?

A more detailed discussion of these procedures is in 49 C.F.R. §§ 107.301 through 107.333. These procedures are also on the Office of the Chief Counsel's home page at "<http://phmsa-attorney.dot.gov>."

**INSTRUCTIONS FOR ELECTRONIC FUNDS TRANSFER TO
THE FEDERAL AVIATION ADMINISTRATION, U.S. DEPARTMENT OF TRANSPORTATION**

1. <u>RECEIVER'S ABA NO.</u> 021030004	2. <u>TYPE SUBTYPE</u> (provided by sending bank)
3. <u>SENDING BANK ABA NO.</u> (Provided by sending bank)	4. <u>SENDING BANK REF NO.</u> (Provided by sending bank)
5. <u>AMOUNT</u>	6. <u>SENDING BANK NAME</u> (Provided by sending bank)
7. <u>RECEIVER NAME:</u> TREAS NYC	8. <u>PRODUCT CODE</u> (Normally CTR, or as provided by sending bank)
9. <u>BENEFICIARY (BFN) - AGENCY LOCATION CODE</u> <u>BNF=/ AC 69-14-0001</u>	10. <u>REASONS FOR PAYMENT</u> Example: PHMSA - Payment for Case # / Ticket Number/Pipeline Assessment number

INSTRUCTIONS: You, as sender of the wire transfer, must provide the sending bank with the information for Block (1), (5), (7), (9), and (10). The information provided in blocks (1), (7), and (9) are constant and remain the same for all wire transfers to Pipeline and Hazardous Materials Safety Administration, Department of Transportation.

Block #1 - RECEIVER ABA NO.- "021030004". Ensure the sending bank enters this nine-digit identification number; it represents the routing symbol for the U.S. Treasury at the Federal Reserve Bank in New York.

Block #5 - AMOUNT - You as the sender provide the amount of the transfer. Please be sure the transfer amount is punctuated with commas and a decimal point. EXAMPLE; \$10,000.00

Block #7 - RECEIVER NAME - "TREAS NYC." Ensure the sending bank enters this abbreviation; it must be used for all wire transfer to the Treasury Department.

Block #9 - BENEFICIARY- AGENCY LOCATION CODE - "BNF=/AC-69140001"
Ensures the sending bank enters this information. This is the Agency Location Code for Pipeline and Hazardous Materials Safety Administration, Department of Transportation.

Block #10 - REASON FOR PAYMENT - "AC-payment for PHMSA Case # / To
ensure your wire transfer is credited properly, enter the case number/ticket number or Pipeline Assessment number, and country."

Note: - A wire transfer must comply with the format and instructions or the Department cannot accept the wire transfer. You, as the sender, can assist this process by notifying, at the time you send the wire transfer to the General Accounting Division (405) 954-8893.



Inspection / Investigation Report No. 05421016

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement

Inspection Location:

Alden Medical, LLC
360 Cold Spring Ave.
West Springfield, MA 01089

Contact: Damon D'Amico, General Manager

Phone: 413-747-9717

Fax:

Type of Inspection: SHIPPER INSPECTION
(GENERAL)

Result: ENFORCEMENT REPORT

Inspector: MICHALSKI, CHRISTOPHER
Code: DHM-42.1
Title: HAZARDOUS MATERIALS
ENFORCEMENT SPECIALIST

Signature:

Inspector #2:
Code:
Title:

Supervisor Name: Colleen Abbenhaus
Title: Chief, Eastern Region

Authorization Date: 4/26/2005

Summary of Inspection

On March 15 and 17, 2005, Chris Michalski, Senior Hazardous Materials Enforcement Specialist, conducted a compliance inspection at Alden Medical, LLC, West Springfield, MA (Alden). Alden is a blender of disinfectant products.

Mr. Damon D'Amico, General Manager, represented Alden during the inspection and provided all requested documentation. He also signed the Exit Briefing (see exhibit 1) and Hazmat Security Inspection Report (see exhibit 2).

On March 16, 2005, Mr. D'Amico notified the inspector that he located the company's security plan, which was not available at the time of the initial inspection. On March 17, 2005, the inspector returned to Alden to review the plan. Mr. D'Amico signed the revised Hazmat Security Inspection Report (see exhibit 3).

Correspondence was submitted by Alden on March 29, 2005.

Violation Number: 1

Number Discovered: 1

49 CFR Section:

Exhibit: 4 - 8

171.2(a), 173.22(a)(4), 173.24(f)(2), 173.202(a)

Violation Description:

Offering for transportation, in commerce, a hazardous material, hydrogen peroxide and peroxyacetic acid mixtures, stabilized, 5.1(8), UN3149, II, in unauthorized packagings, in violation of 49 CFR, §§171.2(a), 173.22(a)(4), 173.24(f)(2) and 173.202(a).

Evidence Summary:

During the compliance inspection at Alden Medical, LLC, West Springfield, MA (Alden), inspector Michalski observed the UN-standard packagings, containing hazardous materials, prepared by Alden for shipment. Among others, the inspector observed four x one-gallon packagings, marked and labeled as containing hydrogen peroxide and peroxyacetic acid mixtures, stabilized, 5.1(8), UN3149, II.

The packagings were certified UN4G/Y25.6/S/04/USA/+AX4497 (see exhibit 4). The symbol +AX belongs to Container-Quinn Testing Laboratories, Inc., Wheeling, IL (CQTL), a DOT approved third party testing laboratory. When reviewing CQTL's test report, for the packagings in question, the inspector noted that (see exhibit 5) CQTL used 2" or 3" wide poly tape to close the packagings. Alden used metal staples (see exhibit 4), a method which was not authorized by CQTL. Mr. Damon D'Amico, General Manager, explained (see exhibit 6) that Alden changed the closure method to staples per a customer's request.

Section 178.602 (a) requires that each packaging must be closed in preparation for testing, and testing must be carried out in the same manner as if prepared for transportation, including inner packagings in the case of combination packagings. Sections 172.22(a)(4) and 172.24(f)(4) require the shipper to perform all functions necessary to bring the package containing a hazardous material into compliance with parts 173 and 178, in accordance with the manufacturer's instructions. Since the closure method for the inner packagings differed, the packagings used by Alden were not tested as configured for shipment, and were not authorized for shipping hazardous materials.

The inspector asked for a copy of the shipping documentation exemplifying a shipment of hydrogen peroxide and peroxyacetic acid mixtures, stabilized, 5.1(8), UN3149, II, previously executed by Alden using packagings closed with metal staples. He was provided with a copy of Alden's bill of lading, dated March 11, 2005 (see exhibit 7) and the Material Safety Data Sheet for the product (see exhibit 8).

Violation Number: 2

Number Discovered: 1

49 CFR Section:

171.2(c), 178.503(a)(2)
CA-0010008

Exhibit: 6, 9 - 11

Violation Description:

Representing, marking, offering and certifying UN4G-standard packagings, when the packagings not marked as prescribed in the approval CA-0010008 and §178.503(a)(2), in violation of 49 CFR, §§171.2(c), 178.503(a)(2) and CA-0010008, dated October 17, 2005.

Evidence Summary:

Same evidence as the previous violation.

During the compliance inspection at Alden Medical, LLC, West Springfield, MA (Alden), inspector Michalski observed UN-standard packagings, marked UN4G/Y5.7/S/04/USA/+AV1584 (see exhibit 9). The symbol +AV belongs to Packaging Design and Testing Corporation of New England, East Granby, CT (PDTC), a DOT approved third party testing laboratory.

When reviewing PDTC's test report, number 1584, dated January 28, 2003 (see exhibit 10), the inspector noted that the testing was conducted on Alden's behalf, under Approval CA-0010008. The certification issued by PDTC, UN4GW/Y7/S/___/USA/+AV1584 did not match the one noted on Alden's packagings. Mr. Damon D'Amico, General Manager, stated (see exhibit 6) that the certification was miss-printed.

Mr. Alden provided a copy of Approval CA-0010008, dated October 17, 2000 (see exhibit 11). The approval authorized Alden to test the packagings differently than prescribed by 49 CFR. The inner packagings are not required to be filled to a minimum 98 percent capacity for testing. Paragraph 5.c. of the approval requires that the packagings be marked UN4GW, in accordance with §178.503(a)(2). Alden did not meet that requirement.

In addition, since the certification on the packagings included a gross mass lower to which tested, use of these packagings would result in the actual gross mass exceeding the one to which certified.

Violation Number: 3

Number Discovered: 1

49 CFR Section:

171.2(a), 172.702(a), 172.704(a)(5)

Exhibit: 2, 7, 8

Violation Description:

Offering for transportation, in commerce, a hazardous material, hydrogen peroxide and peroxyacetic acid mixtures, stabilized, 5.1, UN3149, II, in a placardable quantity, when in-depth security training was not conducted, as prescribed by §172.704(a)(5), in violation of 49 CFR, §§171.2(a), 172.702(a) and 172.704(a)(5).

Evidence Summary:

During the compliance inspection at Alden Medical, LLC, West Springfield, MA (Alden), inspector Michalski obtained a copy of Alden's bill of lading, dated March 11, 2005 (see exhibit 7), which shows that the company shipped 3520 lbs (a placardable quantity) of hydrogen peroxide and peroxyacetic acid mixtures, stabilized, 5.1, UN3149, II. The inspector also obtained a copy of the Material Safety Data Sheet for the product (see exhibit 8).

Section 172.800(b) requires shippers of placardable quantities of hazardous materials to develop a security plan. Section 172.704(a)(4) requires that by December 22, 2003, each hazmat employee of a person required to have a security plan be provided with the in-depth security training concerning the security plan and its implementation.

The inspector interviewed Mr. Damon D'Amico, General Manager, regarding Alden's security plan. Mr. D'Amico indicated (see exhibit 2) that the plan was not yet completed, as the company changed the ownership the previous year.

The next day, Mr. D'Amico contacted the inspector to inform him that the search of the office files revealed that the previous owner prepared a written security plan. On May 17, 2005, the inspector returned to Alden to review the plan, and he determined that it met the requirements of the HM. Mr. D'Amico acknowledged that the in-depth security training involving the plan was yet to be conducted (see exhibit 6).

Violation Number: 4

Number Discovered: 1

49 CFR Section:
171.2(a), 107.601(a)

Exhibit: 6 - 8

Violation Description:

Offering for transportation, in commerce, a hazardous material, hydrogen peroxide and peroxyacetic acid mixtures, stabilized, 5.1, UN3149, II, in a placardable quantity, while failing to register as prescribed by §107.601(a)(6), in violation of 49 CFR, §§171.2(a) and 107.601(a).

Evidence Summary:

During the compliance inspection at Alden Medical, LLC, West Springfield, MA (Alden), inspector Michalski obtained a copy of Alden's bill of lading, dated March 11, 2005 (see exhibit 7), which shows that the company shipped 3520 lbs (a placardable quantity) of a hazardous material, hydrogen peroxide and peroxyacetic acid mixtures, stabilized, 5.1, UN3149, II. The inspector also obtained a copy of the Material Safety Data Sheet for the product (see exhibit 8).

Section 107.601(a)(6) requires that shipments of hazardous materials (hazmat), in quantities requiring placarding, must be registered with RSPA. Section 172.504(b) requires placarding for shipments of one class of a hazmat in excess of 454 kg (1001 lbs).

The inspector questioned Mr. Damon D'Amico, General Manager, regarding Alden's, regarding Alden's hazmat registration. Mr. D'Amico stated (see exhibit 6) that Alden did not register as a shipper of hazardous materials.

Additional Information Pertaining to the Inspection:

Correspondence was submitted by Alden Medical, LLC, on March 29, 2005 (see exhibit 12). The correspondence did not include any evidence of corrective action. The inspector requested documentation of corrective action on April 20, 2005 (see exhibit 13).

Documentation was submitted by Alden Medical, LLC, on April 26 and 28, 2005, shows that the company corrected the discrepancies noted during the inspection (see exhibit 14).

Exhibit Summary

Evidence		Obtained From		
No.	Description	Name, Title	Company	City, State
1	Exit briefing, dated March 15, 2005	Chris Michalski, SHMES	US DOT	West Trenton, NJ
2	Hazmat Security Inspection Report, dated March 15, 2005	Chris Michalski, SHMES	US DOT	West Trenton, NJ
3	Revised Hazmat Security Inspection Report, dated March 17, 2005	Chris Michalski, SHMES	US DOT	West Trenton, NJ
4	Photographs	Chris Michalski, SHMES	US DOT	West Trenton, NJ
5	Test report, number 11319, dated June 30, 2004	Steve Powell, Laboratory Technician	Container-Quinn Testing Laboratories, Inc.	Wheeling, IL
6	Oral statement	Damon D'Amico, General Manager	Alden Medical, LLC	West Springfield, MA
7	Bill of lading, dated March 11, 2005	Damon D'Amico, General Manager	Alden Medical, LLC	West Springfield, MA
8	Material Safety Data Sheet	Damon D'Amico, General Manager	Alden Medical, LLC	West Springfield, MA
9	Photographs	Chris Michalski, SHMES	US DOT	West Trenton, NJ
10	Test report, number 1584, dated January 28, 2003	Damon D'Amico, General Manager	Alden Medical, LLC	West Springfield, MA
11	RSPA Approval CA-0010008, dated October 17, 2000	Damon D'Amico, General Manager	Alden Medical, LLC	West Springfield, MA
12	Correspondence, dated March 29, 2005	Damon D'Amico, General Manager	Alden Medical, LLC	West Springfield, MA

Alden Medical, LLC**Inspection / Investigation Report No. 05421016**

Evidence		Obtained From		
No.	Description	Name, Title	Company	City, State
13	Email, dated April 20, 2005	Chris Michalski, SHMES	US DOT	West Trenton, NJ
14	Correspondence, dated April 26 and 28, 2005	Damon D'Amico, General Manager	Alden Medical, LLC	West Springfield, MA



US Department
of Transportation

Pipeline and Hazardous
Materials Safety Administration

Office of Hazardous
Materials Enforcement
Eastern Region

820 Bear Tavern Rd., Ste. 306
West Trenton, NJ 08628
(609)989-2256
(609)989-2277 Fax

EXIT BRIEFING

(This document is not a final report.)

Date: 3/15/05 Report Control #: _____

Company Name: ALDRIN MEDICAL LLC

Address: 360 COLD SPRING AVE, WEST SPRINGFIELD
MA 01089

NAME OF INDIVIDUALS RECEIVING BRIEFING:

Name: DAMON D'AMICO Title: PRESIDENT

Name: _____ Title: _____

Name: _____ Title: _____

This has been a compliance inspection conducted in accordance with Title 49 U.S.C. Section 5121(c). This exit briefing addresses only the areas noted, and it is not a finding of general compliance in any other areas covered by the Hazardous Materials Regulations that were subject to the inspection.

During the course of the inspection the following probable violations of 49 CFR and/or quality control items were noted:

PROBABLE VIOLATIONS:

Section: _____
Explanation: 173.24(f)(2)

PACKAGES MUST BE CLOSED IN ACCORDANCE WITH THE
MANUFACTURER'S CLOSURE INSTRUCTIONS

Section: _____
Explanation: 178.503(c)(2)

THE LETTER N MUST APPEAR IN THE UN
CERTIFICATION OF PACKAGINGS TESTED
UNDER A SPECIAL APPROVAL. GROSS MASS
MUST NOT EXCEED THE ONE SHOWN IN THE CERT

U.S. DOT/PHMSA/OHME/EASTERN REGION
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PROBABLE VIOLATIONS:

Section: _____

Explanation: 172. 800

SHIPPERS OF PLACARDABLE QUANTITIES
OF HAZMAT ARE REQUIRED TO DEVELOP
SECURITY PLANS (INCLUDING IN-DEPTH TRNG)

Section: _____

Explanation: 107. 601

SHIPPERS OF PLACARDABLE QUANTITIES
OF HAZMAT ARE REQUIRED TO REGISTER

Section: _____

Explanation: _____

Section: _____

Explanation: _____

Section: _____

Explanation: _____

Report Control #: _____

This document is not a final report. The information gathered at this inspection and any probable violations noted will be reviewed prior to finalizing the report. Probable violation(s) may be removed or others may be added during this review. In addition, quality control items may be revised to become probable violations during this review.

Upon determination that a probable violation exists, the Associate Administrator for Hazardous Materials Safety is authorized to impose certain sanctions, including warning letters, compliance orders, and civil penalties. In addition, court actions, including injunctive or criminal proceedings, may be initiated. Title 49 U.S.C. Sections 5123 and 5124 provide for civil and criminal penalties for violation of the Hazardous Materials Regulations.

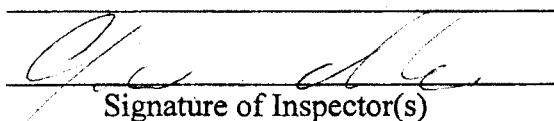
A civil penalty of not more than \$32,500, but not less than \$275, per violation may be imposed through administrative proceedings initiated by the Office of Chief Counsel of the Pipeline and Hazardous Materials Safety Administration. When a criminal violation has been determined by a court, a fine, or imprisonment for not more than 5 years, or both, may be imposed for each violation.

The inspector does not determine which sanction, if any, may be imposed and cannot provide information concerning what proceedings will be initiated or sanctions imposed.

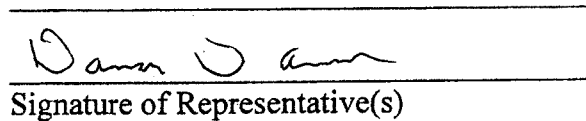
Documentation of corrective action submitted in writing to the inspector within 30 days of the inspection may be considered for mitigation should the sanction imposed result in the issuance of a notice proposing a civil penalty. However, any documented corrective action would not eliminate or preclude the initiation of a civil penalty proceeding, a finding of violation, or assessment of a civil penalty.

Our objective is to ensure a fair regulatory enforcement environment. If you feel you have been treated unfairly or unprofessionally, you may contact John J. O'Connell, Jr. at 202-366-4700, or e-mail us at OHME-HQ@dot.gov. You also have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities by this agency. The Pipeline and Hazardous Material Safety Administration strictly forbids retaliatory acts by its employees. As such, you should feel confident that you will not be penalized for expressing your concerns about compliance and enforcement activities.

I certify that I received the above briefing as it appears on this form. I understand that by signing this form I am in no way expressing agreement with its contents. I am only acknowledging that I have reviewed it and have received a copy.


Signature of Inspector(s)

3/15/05
Date


Signature of Representative(s)

3/15/05
Date

U.S. DOT/PHMSA/OHME/EASTERN REGION
REPORT # 05421016
EXHIBIT # 1
PAGE 3 OF 3

INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES



PIPELINE AND HAZARDOUS MATERIAL SAFETY
ADMINISTRATION HAZMAT SECURITY INSPECTION



Inspection Date: 3/15/05

Facility Name and Address: ALDEN MEDICAL LLC
360 COLD SPRING AVE
WEST SPRINGFIELD MA 01089

Company Officials Interviewed:

DAMON D'AMICO

Title:

RESIDENT

1. Does the company offer any of the following for transportation:[§ 172.800(b)]

- ☐ a) A highway route controlled quantity of a Class 7 material.
- ☐ b) More than 55 pounds of a Division 1.1, 1.2, 1.3 in a motor vehicle, rail car, or freight container.
- ☐ c) More than 1 liter per package, of a material poison by inhalation, Zone A.
- ☐ d) A quantity of a hazardous material in a bulk packaging (> 3,500 gallons for liquids/gas, 468 cubic feet for solids).
- ☐ e) >5,000 lbs. (gw) of one hazard class in non-bulk packaging for which placarding of a vehicle, rail car or freight container is required.
- ☐ f) A select agent or toxin listed in 42 CFR, Part 73.
- ☒ g) A quantity of hazardous materials that requires placarding

2. Does the company have a written security plan?

YES NO

3. Has it been approved by another Federal agency [172.804]?

4. If yes, name of agency _____ and date approved _____

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INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

5. Does the plan include a security assessment of possible transportation security risks [172.802]?

6. Does the plan include measures to address the assessed risk(s)?

7. Does the plan address personnel security?

8. What method is in place to confirm information provided by employees hired for positions that involve access to or handling of materials covered by the security plan?

N/A

9. Is the company adhering to its personnel security plan?

10. Does the plan address unauthorized access?

11. Does the company adhere to the plan to prevent unauthorized persons to gain access to hazmat covered by the plan or transport conveyances being prepared for transportation?

U.S. DOT/PHMSA/OHME	
Report#	<u>05421016</u>
Exhibit #	<u>2</u>
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INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

12. Does the plan address en route security?

13. Does the company adhere to its en route security plan from origin to destination, including private/contract/common carrier?

SECURITY TRAINING

14. Has the company conducted security awareness training (SAT)? * YES

15. Does the security awareness training include a component on how to recognize and respond to possible security threats? YES

16. Has each HM employee, hired after March 25, 2003, received SAT within 90 days of hire?

YES

17. Has the company conducted in-depth security training (plan specific) for all HM employees by December 22, 2003? NO

18. Does the in-depth training program include the following:

a. Company security objectives? _____

b. Specific security objectives? _____

c. Employee responsibilities? Cur

d. Actions to take in the event of a security breach? _____

e. Organizational security structure? _____

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INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

19. Has the company created and retained records of employee security training?

YES

Additional Notes

WORK-IN-PROGRESS : UPDATING SECURITY PLAN

PRIOR TO DEVELOPING THIS PLAN : NEW TRAINING

AND SECURITY SYSTEM COMPLETED

[* Note: A company is not required to test or retain records concerning the new security plan training requirement until an employee's next scheduled retraining or within the 3 year Hazmat Employee training cycle.]

This inspection report assesses your compliance with our Security Plan regulations (49 CFR §§ 172.704 (Training), 172.800 (Purpose and Applicability), 172.802 (Components of a security plan), and 172.804 (Relationship to other Federal requirements)). **This inspection report and any comments made during this evaluation do not constitute an endorsement or approval of your security program in whole or in part. Do not send us a copy of your Security Plan as a part of corrective action. If we need a copy of your Security Plan we will specifically request it in writing.**

I hereby certify that the above responses are true to the best of my knowledge.

Persons Interviewed:

Signature Dan Dan Title General MGR Date 3/15/05

Signature _____ Title _____ Date _____

Inspector(s):

Signature [Signature] Title SUPERVISOR Date 3/15/05

Signature _____ Title _____ Date _____

Nothing Follows. cu (Inspector's Initials)

The following website may be helpful in the development and administration of security plans:

http://hazmat.dot.gov/hmt_security.htm

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INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

**INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES**

REVISED



**PIPELINE AND HAZARDOUS MATERIAL SAFETY
ADMINISTRATION HAZMAT SECURITY INSPECTION**



Inspection Date: 3/17/05

Facility Name and Address: ALDIEN MEDICAL LLC
360 COLD SPRING AVE
WEST SPRINGFIELD MA 01089

Company Officials Interviewed: DAMON D'AMICO Title: PRESIDENT

1. Does the company offer any of the following for transportation:[§ 172.800(b)]
- ☐ a) A highway route controlled quantity of a Class 7 material.
 - ☐ b) More than 55 pounds of a Division 1.1, 1.2, 1.3 in a motor vehicle, rail car, or freight container.
 - ☐ c) More than 1 liter per package, of a material poison by inhalation, Zone A.
 - ☐ d) A quantity of a hazardous material in a bulk packaging (> 3,500 gallons for liquids/gas, 468 cubic feet for solids).
 - ☐ e) >5,000 lbs. (gw) of one hazard class in non-bulk packaging for which placarding of a vehicle, rail car or freight container is required.
 - ☐ f) A select agent or toxin listed in 42 CFR, Part 73.
 - ☒ g) A quantity of hazardous materials that requires placarding
2. Does the company have a written security plan?
YES
3. Has it been approved by another Federal agency [172.804]?
N/A
4. If yes, name of agency N/A and date approved _____

U.S. DOT/PHMSA/OHME	
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**INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES**

INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

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6. Does the plan include measures to address the assessed risk(s)?

YES

7. Does the plan address personnel security?

YES

8. What method is in place to confirm information provided by employees hired for positions that involve access to or handling of materials covered by the security plan?

VERIFICATION OF THE IDENTITY

9. Is the company adhering to its personnel security plan?

YES

10. Does the plan address unauthorized access?

YES

11. Does the company adhere to the plan to prevent unauthorized persons to gain access to hazmat covered by the plan or transport conveyances being prepared for transportation?

YES

U.S. DOT/PHMSA/OHME	
Report#	<u>05421016</u>
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INVESTIGATIVE NOTES
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COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

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YES

SECURITY TRAINING

14. Has the company conducted security awareness training (SAT)? *

YES

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YES

16. Has each HM employee, hired after March 25, 2003, received SAT within 90 days of hire?

YES

17. Has the company conducted in-depth security training (plan specific) for all HM employees by December 22, 2003?

NO

18. Does the in-depth training program include the following:

a. Company security objectives?

b. Specific security objectives?

c. Employee responsibilities?

d. Actions to take in the event of a security breach?

e. Organizational security structure?

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INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

19. Has the company created and retained records of employee security training?

GENERAL AWARENESS DONE BY OUTSIDE SOURCE M-BETH

Additional Notes

TRAINING NOT FORMALIZED

THE SECURITY PLAN WAS CREATED ON APRIL 15, 2004. IT

SHOULD INCLUDE MORE DETAIL AS TO THE MEASURES BEING

TAKEN BY THE COMPANY TO COMPLY WITH EACH OF THE COMPONENTS

[* Note: A company is not required to test or retain records concerning the new security plan training requirement until an employee's next scheduled retraining or within the 3 year Hazmat Employee training cycle.]

This inspection report assesses your compliance with our Security Plan regulations (49 CFR §§ 172.704 (Training), 172.800 (Purpose and Applicability), 172.802 (Components of a security plan), and 172.804 (Relationship to other Federal requirements)). **This inspection report and any comments made during this evaluation do not constitute an endorsement or approval of your security program in whole or in part. Do not send us a copy of your Security Plan as a part of corrective action. If we need a copy of your Security Plan we will specifically request it in writing.**

I hereby certify that the above responses are true to the best of my knowledge.

Persons Interviewed:

Signature Dan Damm Title President Date 3/17/05

Signature _____ Title _____ Date _____

Inspector(s):

Signature Chris Allen Title SMCS Date 3/17/05

Signature _____ Title _____ Date _____

Nothing Follows. _____ (Inspector's Initials)

The following website may be helpful in the development and administration of security plans:

http://hazmat.dot.gov/hmt_security.htm

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INVESTIGATIVE NOTES
COMPILED AND RETAINED FOR ENFORCEMENT PURPOSES

**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

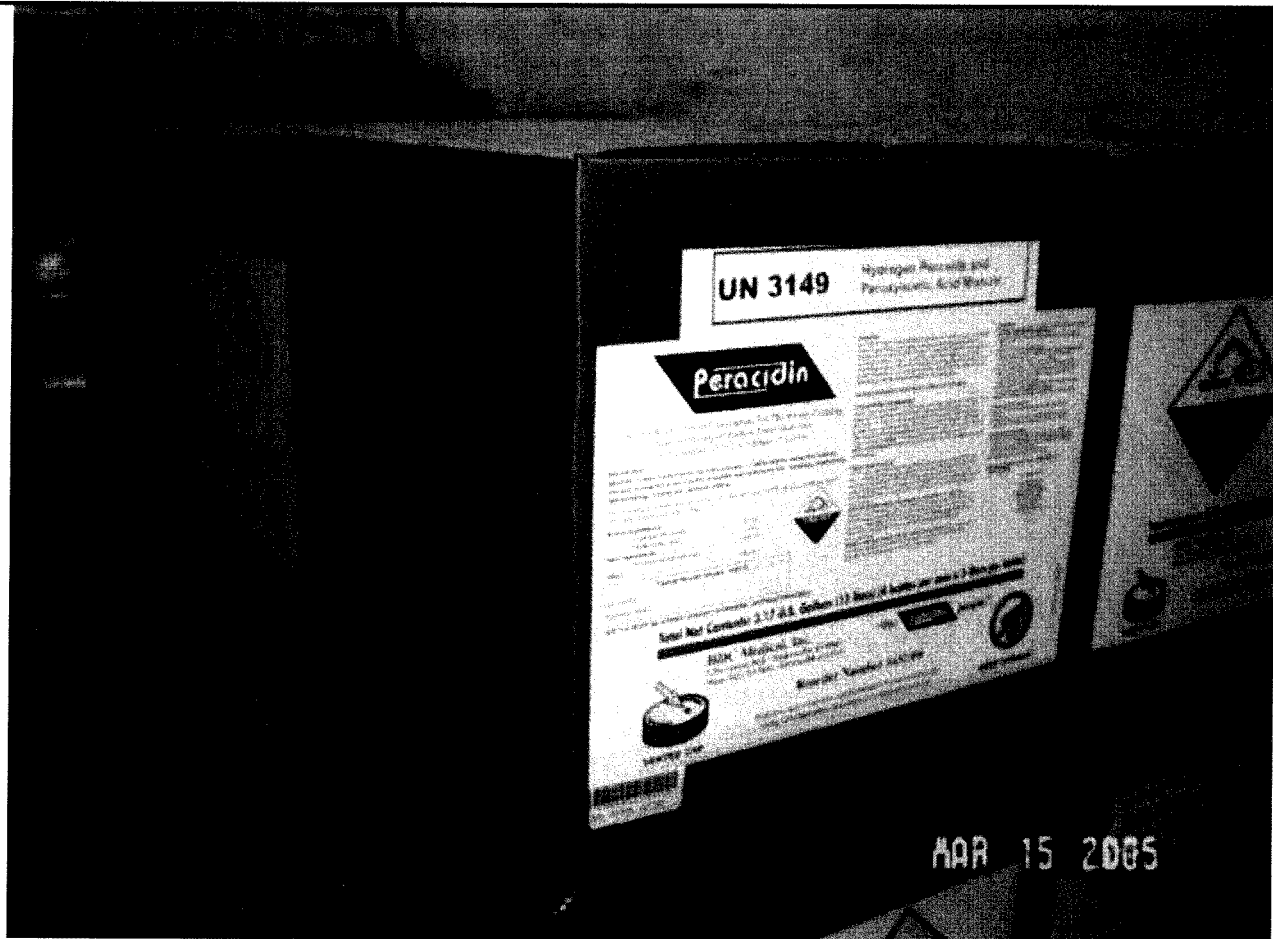
March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

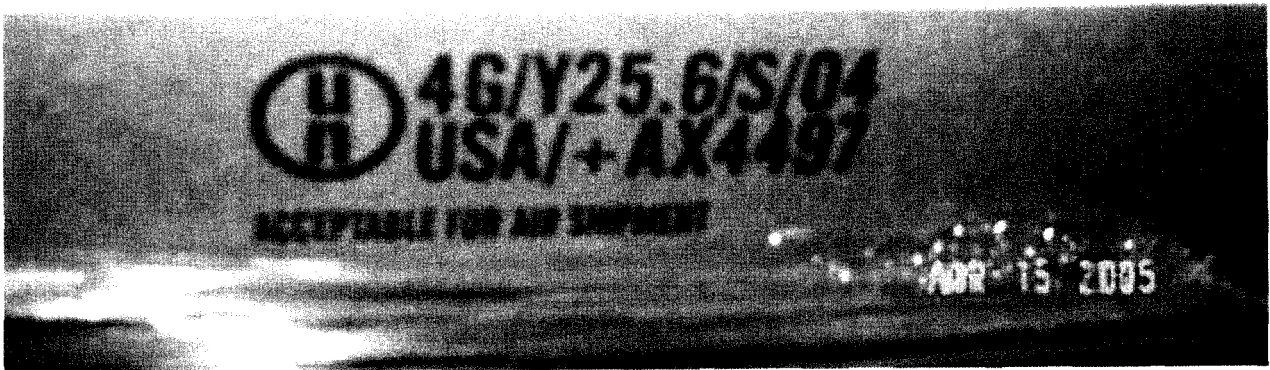
March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

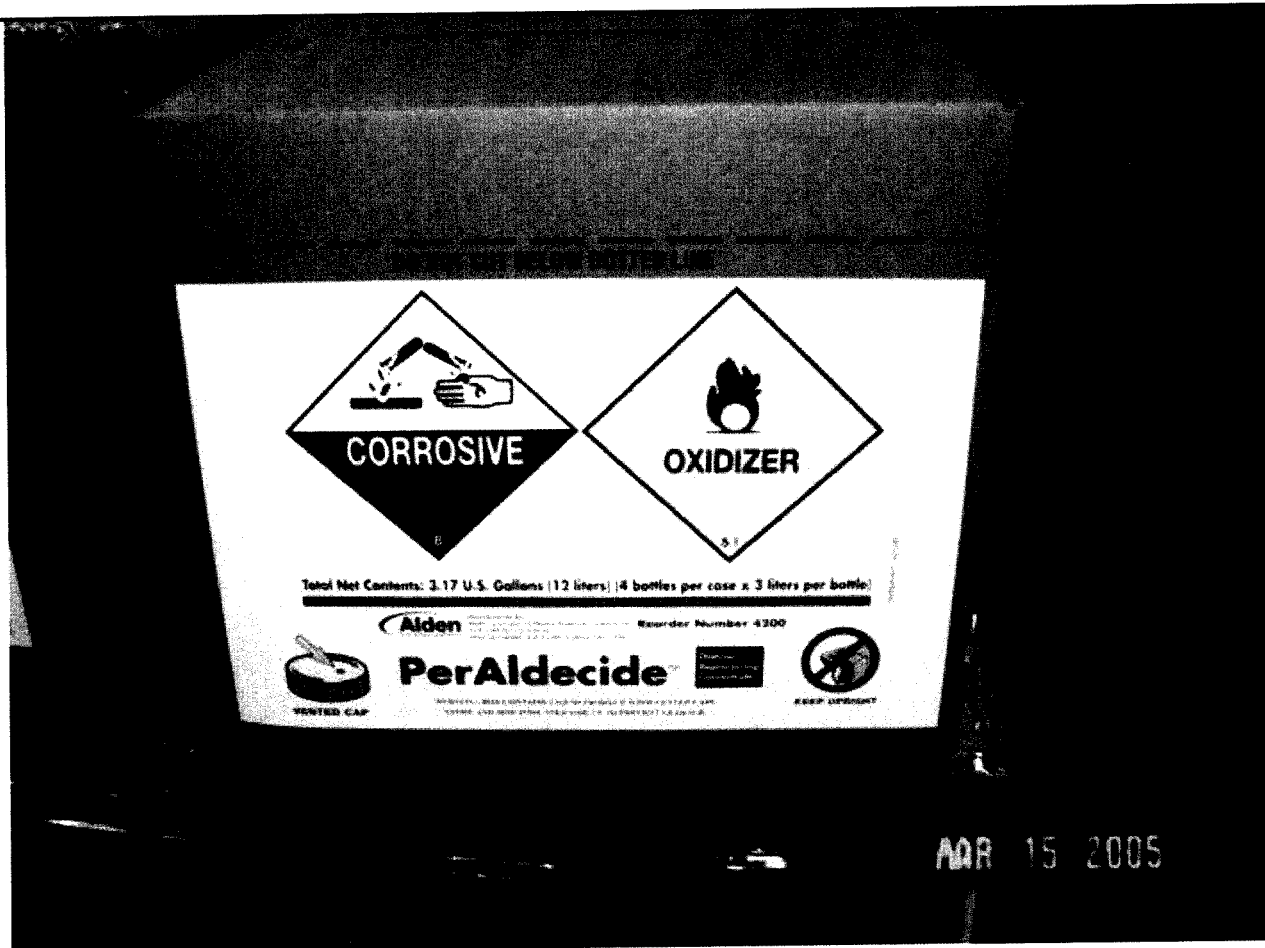
March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
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LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
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LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski





**CONTAINER-QUINN
TESTING LABORATORIES, INC.**

170 Shepard Avenue, Wheeling, IL 60090
Phone: 847-537-9470 Fax: 847-537-9098
E-Mail: spowell@container-quinn.com

TEST CONDUCTED FOR: Silgan Plastics Corporation
P.O. Box 29 - 690 Woodland Drive
Ottawa, OH 45875

Attn.: Michael J. Schneeg

ITEMS TESTED: One (1) sample set of combination packages intended for the transport of Hazardous Materials in Class 3, 8 or 9

Description:

Box: 275# (69-26C-56) / RSC style / "C" flute / glued mfr's. joint
Box USA, Hartford City, IN

Printed I.D.: C-UN-3; C-UN-4

Dimensions (O.D.): 13" x 12 3/4" x 13 5/8"

Specific Gravity: Not to exceed 1.6

Interior Packaging: (4) 1-gallon round HDPE poly bottles (120 gm) with handles and four (4) 38/400 plastic screw-cap closure styles as follows:
#1 - ribbed, Top Seal CRC, foam lined; #2 - fine-ribbed, Phoenix flat cap, foam lined; #3 - fine-ribbed, Polyseal flat cap, foam lined and #4 - fine-ribbed, OI CRC, foam lined
(1) Full-size D/C special design DW (B/C) corrugated top positioning insert (42-33C-42-33B-42)(trapezoid style)

Nominal Gross Weight: 56.4 lbs. (25.6 kg)

Closures: (top) 2" wide or 3" wide p.s. poly tape or equivalent
(bottom) Hot melt adhesive or 2" wide or 3" wide p.s. poly tape or equivalent

OBJECT OF TEST: To determine the compliance with applicable sections of the United Nations recommendations for the transport of dangerous goods and the Department of Transportation's Title 49 Code of Federal Regulations ((CFR), Part 178: Subpart M - Testing of Non-bulk Packagings and Packages

Packaging Code Designation	Packing Group
4G Fiberboard Box	II Moderate Danger Hazardous Material

CERTIFICATION NUMBER: +AX4497

Note: Photograph on file

CONTAINER-QUINN TESTING LABORATORIES, INC.

U.S. DOT/PHMSA/OHME/EASTERN
REPORT # 05421010
EXHIBIT # 15
PAGE 1 OF 7

APPROVED BY:

Stephen C. Powell - Laboratory Director

AS A MUTUAL PROTECTION FOR OUR CLIENTS AND OURSELVES, ALL REPORTS ARE SUBMITTED AS THE CONFIDENTIAL PROPERTY OF OUR CLIENTS, AND AUTHORIZATION FOR PUBLICATION IS RESERVED PENDING WRITTEN APPROVAL.

SAMPLES WILL BE DISPOSED OF 30 DAYS AFTER TESTING IS COMPLETED UNLESS OTHER ARRANGEMENTS ARE AGREED TO IN WRITING



TEST PROCEDURE AND RESULTS
REPETITIVE SHOCK VIBRATION TEST

SAMPLE SIZE

3 Boxes, each style cap

TABLE DISPLACEMENT

1"

TEST FREQUENCY

4.1 Hz

CONDITIONING

Ambient

TEST STANDARD

49 CFR; Section 178.608

ASTM D-999

EQUIPMENT

Lansmont Vibration Table

TEST DURATION

1-Hour (60 Minutes)

REPETITIVE SHOCK VIBRATION TEST RESULTS

BOX	RESULT	OVERALL SUMMARY
1	PASSED	No deterioration / damage / product leakage
2	PASSED	
3	PASSED	



TEST PROCEDURE AND RESULTS
STACK TEST

SAMPLE SIZE

3 Boxes each style cap

TEST STANDARD

49 CFR; Section 178.606
UN Recommendations 9.7.6

TEST LOAD

Based on 118.11" (3m) stack height
Box height - approx 13 5/8"
7.6 boxes on top to attain 118.11" height
7.6 x 56.4 = 433 lbs. Load
Load Applied - 435 lbs.

TEST DURATION

24-hours

CONDITIONING

Ambient

STACK TEST RESULTS

BOX	RESULT	MAXIMUM DEFLECTION AFTER 24-HOURS	OVERALL SUMMARY
1	PASSED	0"	No deflection No deterioration No damage
2	PASSED	0"	
3	PASSED	0"	



TEST PROCEDURE AND RESULTS
DROP TEST

SAMPLE SIZE

5 Boxes each style cap

PACKAGE TEST WEIGHT

37.4 lbs.

DROP HEIGHT

1.6m (~63.0")

CONDITIONING

-18+/-3° C and Ambient RH

DROP TEST EQUIPMENT

Split Table Drop Tester

TEST STANDARD

49 CFR; Section 178.603

UN Recommendations 9.7.3

ASTM D-997

DROP HEIGHT CALCULATION

Specific Gravity: 1.55

Packaging Group: II

Calculation: 1.6 x 1.0m

Drop Height: 1.6m

BOTTLE CAPACITY

1.03-gallons

DROP TEST RESULTS

BOX	DROP	RESULT	OVERALL SUMMARY
1	Top	PASSED	Normal and expected packaging fatigue and crush
2	Bottom	PASSED	
3	Sm Side	PASSED	
4	Lg Side	PASSED	
5	Corner	PASSED	



TEST PROCEDURE AND RESULTS
INTERNAL (HYDROSTATIC) PRESSURE TESTING

SAMPLE SIZE

3 Bottles each style cap

FILLING SUBSTANCE

Water

FILL LEVEL

Overflow Capacity

TEST PRESSURE

100 kPa (14.5 psi)

TEST DURATION

30 Minutes

TEST STANDARD

49CFR; Section 178.605

UN Recommendations 9.7.5

EQUIPMENT

Regulated Water Source

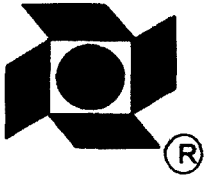
Pressure Monitoring Gauge

CLOSURE TORQUE

17 - 25 in-lbs.

INTERNAL (HYDROSTATIC) PRESSURE TEST RESULTS

BOTTLE	RESULT	OVERALL SUMMARY
1	PASSED	No leakage noted
2	PASSED	
3	PASSED	



TEST PROCEDURE AND RESULTS
COBB WATER ABSORPTION TEST

SAMPLE SIZE

3 Samples

FILLING SUBSTANCE

Water

FILL LEVEL

100 ml

TEST DURATION

30 Minutes

TEST STANDARDS

49 CFR; Section 178.516

UN Recommendations 9.6.11.1

TEST EQUIPMENT

COBB Water Absorption Tester

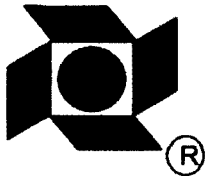
100 ml capacity test beaker

Stop Watch

COBB WATER ABSORPTION TEST RESULTS

SAMPLE	RESULT	OVERALL SUMMARY
1	130	PASSED
2	120	
3	130	

U.S. DOT/PHMSA/OHME/EASTERN
REPORT # 05421016
EXHIBIT # 3
PAGE 6 OF 7



DOT / UN PACKAGING CERTIFICATION

CONTAINER-QUINN TESTING LABORATORIES, INC. certifies that the previously described testing services have performed in accordance with standard good laboratory practices and that the packaging tested has passed the standards of the DEPARTMENT OF TRANSPORTATIONS TITLE 49 CFR, PERFORMANCE ORIENTED PACKAGING STANDARDS, SECTION 178, in accordance with CODE 4G, Packing Group II, Moderate Danger Hazardous Materials

It is the responsibility of the end user to determine authorization for use under these regulations. All other warranties, expressed or implied, including any warranty that the packaging tested is merchantable or fit for a particular purpose, are disclaimed.

In no event shall Container-Quinn Testing Laboratory, Inc. liability exceed the total amount paid by Silgan Plastics Corporation for services rendered.

In the event of future changes to the above referenced Test Standard, it is the responsibility of Silgan Plastics Corporation to determine whether additional testing or updating of past testing is necessary to verify that the packaging tested remains in compliance with those standards

4G FIBERBOARD BOX WITH INNER PACKAGING

UN MARKING:



4G / Y 25.6 / S / 04
USA / +AX4497

TEST REPORT NUMBER(s)

11319

PACKAGING CERTIFICATION AGENCY: CONTAINER-QUINN TESTING LAB (+AX)

PACKAGING IDENTIFICATION CODE: 4G

AUTHORIZED PACKING GROUP(S): II (Y) and III (Z)

MAXIMUM PRODUCT GROSS MASS: 25.6 kg (56.4 lbs.)

"S" DESIGNATION: Denotes inner packaging

YEAR OF MANUFACTURE: 2004

STATE AUTHORIZING THE MARK: USA

PERIODIC RETEST DATE: 30 June 2006

**U.S Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Oral Interview Form**

Inspectors Conducting Interview Name: Chris Michalski Title: Senior Hazardous Materials Enforcement Specialist Report Number: 05421016	Respondent Company: Alden medical, LLC. Address: West Springfield, MA
Person Interviewed Name: Damon D'Amico Title: General Manager Company: Alden Medical, LLC. City/State: West Springfield, MA	Date and Type of Interview Date: March 15 and 17, 2005 In Person: X Telephone:

SUBSTANCE OF INQUIRY AND ANSWER GIVEN (NOT A TRANSCRIPT)

Inspector – (I), Respondent – (R).

(I): The test report for the certification +AX4497 shows that the packagings were closed with poly tape for testing, while you use metal staples to close them. Did you obtain any additional closure instructions or test reports for these packagings that would authorize this change of closure?

(R): No, we close the boxes with staples per our customer's request.

(I): The UN-certification on your packagings does not match the one in the test report you gave me. Can you explain that?

(R): I am not sure how this happened, but it is an obvious miss-print. The certification should include the letter W, as the packagings were tested under the approval I received from RSPA.

(I): Your shipping records show that you ship placardable quantities of hazardous materials. Are you registered with RSPA as a shipper of hazardous materials?

(R): No.

(I): Similarly, there is a requirement for shippers of placardable quantities of hazardous materials to develop a security plan. Do you have such a plan?

(R): No, not yet. I purchased this company last year and I have been working on improving the facility's security. I still have to put it in writing.

**U.S Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement**

March 17, 2005

(I): You told me before that you did not have a written plan, but now you are presenting me with one. Can you explain that?

(R): As I mentioned before, I recently purchased this company. After you left, I searched my predecessor's files and I found this plan, which was prepared prior to my acquiring the company. I was working on some of the implementations not realizing that the plan was already written.

(I): Since you were not aware of the existence of the plan, does it mean that the in-depth security training involving this plan was not yet accomplished?

(R): That is correct.

OVERNITE

STRAIGHT BILL OF LADING - SHIPPING ORDER NOT NEGOTIABLE - DOMESTIC
OVERNITE TRANSPORTATION COMPANY (OVNT) PLEASE PRINT OR TYPE

DATE

7/11/95

1. CONSIGNEE (TO)

On collect on delivery shipments, the letters "COD" must appear before consignee's name or as otherwise provided in item 430, Sec. 1 of OVNT 102.

STREET ADDRESS

OVERNITE CANNOT DELIVER TO A P.O. BOX

CITY

STATE

ZIP (REQUIRED)

P.O. NUMBER

STORE #

DEPARTMENT #

CONSIGNEE PHONE #

CONTACT NAME (ATTN)

3. BILL TO

HDC MEDICAL
c/o NORTHERN CONTINENTAL LOGISTICS

ADDRESS

204 EARL STREET, SUITE 301

CITY

NEW ALBANY, IN

STATE

47150

2. SHIPPER (FROM)

HDC MEDICAL

STREET ADDRESS

360 COLD SPRING AVE.

CITY

WEST SPRINGFIELD, MA

STATE

ZIP (REQUIRED)

01089

BILL OF LADING NUMBER

STORE #

DEPARTMENT #

FREIGHT CHARGES ARE PREPAID UNLESS OTHERWISE MARKED

CHECK ONE: ☒ Prepaid ☐ Collect ☐ Third Party Prepaid

Received \$ _____ to be delivered in the prepayment of the charges on the product described hereon. (Agent or Cashier)

GUARANTEED DELIVERY REQUESTED (if box is checked)

GRTD

By checking this box, the Payor requests Carrier to guarantee delivery of this shipment according to Carrier's transit schedule and agrees to pay 25% (\$30 minimum) above the cost normally incurred for this service. Payor will not be liable for payment if shipment fails to deliver on the scheduled day. Section 7 signature is not valid on Guaranteed Service. Guaranteed service is subject to the conditions of OVNT 20341 Series tariff.

4. NO. PCS.	PKG TYPE	HM*	DESCRIPTION OF ARTICLES & SPECIAL MARKS	WEIGHT (lbs.)	NMFC NO.	CLASS
10	CS	X	HYDROGEN PEROXIDE and PEROXYACETIC ACID MIXTURES, STABILIZED 5.1, UN3149, PG II CHEM EMERGENCY 24 HR. #1-800-424-9300	3,520	43940	85
	BX		KIT BOX		154350-S2	77.5
	BT		409 CLEANER		48581	55
DO NOT FREEZE						
TOTAL CUBE:				2 skids 70 3593		

*Mark with an "X" to designate hazardous materials as defined in title 49 of the Code of Fed. Reg. Hazardous material emergency contact #

5. ADDITIONAL SERVICES: (CHARGES MAY APPLY)

- ☒ INSIDE DELIVERY REQUIRED ☐ RESIDENTIAL DELIVERY
☐ LIFT GATE PICKUP/DELIVERY ☐ SORT AND SEGREGATE
☐ NOTIFICATION BEFORE DELIVERY ☐ OTHER: _____

REMIT C.O.D. CASH / CHECK TO

METHOD OF PAYMENT (REQUIRED)
FEE COLLECT UNLESS OTHERWISE MARKEDCOD FEE ☐ PREPAID ☐ COLLECT

COD SHIPMENTS GOVERNED BY OVNT 102 RULES ITEM 430

COD AMT \$

IF NOT CHECKED, BOTH ARE ACCEPTABLE

☐ CONSIGNEE CHECK ACCEPTABLE ☐ CERTIFIED CHECK OR CASH

CARRIER LIABILITY: Carrier liability for loss or damage will be the lesser of (1) the actual invoice value of the commodities or article(s) lost, damaged or destroyed; or (2) the amount determined from applicable liability provisions of the NMFC; or (3) the limited liability as stated in the applicable governing tariffs, unless "Excess Declared Value Coverage is specifically requested along with the amount of coverage provided in writing on the bill of lading at the time of shipment and applicable charges are paid. Maximum carrier liability is limited to \$25.00 per pound per package and \$100,000 per shipment. Liability for commodities other than new is limited to \$10 per pound per package (and up to a maximum \$2.50 per pound per package when Excess Declared Value Coverage is requested). Liability for specific commodities as provided in the OVNT 102 rules tariff item 166 section 5 is limited to \$2.00 per pound per package. Liability for commodities or articles subject to an exception rating (FAK) is limited as described in the tariff. Certain items may be subject to a limited declared value, with a choice of rates under the tariff. You are advised to review the applicable tariff provisions before stating a value. ** Refer to the current OVNT 102 series for complete details. *Where a "rate" is dependent on a released, declared or actual value in the NMFC, the released, declared or actual value of the property is hereby specifically stated by the shipper to be not exceeding _____ per _____ **Shipper requests Excess Declared Value Coverage in the amount of \$ _____

RECEIVED, subject to individually determined rates or contracts that have been agreed upon in writing between the carrier and shipper, if applicable, otherwise to the rates, classifications and rules that have been established by the carrier and are available to the shipper, on request; *** the property described above in apparent good order, except as noted (contents and condition of contents of packages unknown) marked, consigned, and destined as shown below, which said carrier agrees to carry to destination, if on its route, or otherwise to deliver to another carrier on the route to destination. Every service to be performed hereunder shall be subject to all the conditions not prohibited by law, whether printed or written, herein contained, including the conditions on the back hereof, which are hereby agreed to by the shipper and accepted for himself and his assigns. Where a third party bill to or broker exists, carrier holds both the shipper and consignees liable for freight charges.

Subject to Section 7 Terms and Conditions, if this shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall execute the following statement. The carrier may decline to make delivery of this shipment without payment of freight and all other lawful charges.

(Signature)

LIMITATIONS OF LIABILITY APPLY. SEE OVNT 102 FOR DETAILS
CUSTOMER SERVICE 1-800-333-7400

SPR 524 348 580

TRAILER NUMBER:	LINEAR FEET OF SHIPMENT:
SEAL # APPLIED:	
BEYOND SCAC:	CROSS REF PRO#:
<input type="checkbox"/> SHIPPER LOAD / CONSIGNEE UNLOAD	
U.S. DOT/PHMSA/CHME/EASTERN REPORT # 05421016 EXHIBIT # 7 PAGE 1 OF 1	

This is to certify that the above named materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation.

HDC MEDICAL

Firm name: _____

Signed By: _____

OTC 100 (Rev. 12/93)

OVERNITE

Carrier: _____

Date received: _____

SHIPPER COPY

Driver: _____

Carrier piece count: _____

MATERIAL SAFETY DATA SHEET

PERALDECIDE

Dialyzer Reprocessing Concentrate

1 - IDENTIFICATION

Manufacturer: Alden Medical LLC
Address: 360 Cold Spring Avenue
City, State, Zip: West Springfield, MA 01089
Telephone: 1-413-747-9717
24-Hour Emergency: Chemtrec 1-800-424-9300
Date Prepared: June 16, 2004

2 - COMPOSITION INFORMATION

Hazardous Ingredients

	CAS #	PEL	TLV	%
Acetic Acid	67-19-7	10ppm	10ppm TWA	6.7
Hydrogen Peroxide	7722-84-1	1 ppm	1.4 mg/m ³	27
Peroxyacetic Acid	79-21-0	N/A	N/A	4.5

Other Ingredients

	CAS #	PEL	TLV	%
Water and other inert ingredients	N/A	N/A	N/A	61.8

3 - PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point: 200 °F
Specific Gravity (H₂O = 1): 1.12
Vapor Pressure (mm Hg): N/A
Vapor Density (AIR = 1): N/A
Solubility in Water: Complete
Appearance/Odor: Colorless and sharp, pungent odor
pH: 2.5 (1%)

4 - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): N/A
Flammable Limits: LEL: N/A UEL: N/A
Extinguishing Media: Water spray
Special Fire Fighting Procedures: Normal fire-fighting procedures may be used. Use caution when approaching fire exposed containers.
Unusual Fire and Explosion Hazards: Product decomposes and will release oxygen, thereby adding to the hazard of a fire. Product should be kept cool and in a vented container to avoid any explosion hazards.

5 - REACTIVITY DATA

Stability: Stable under normal conditions of handling
Conditions to Avoid: Do not mix with anything except water. Avoid hot storage.
Incompatibility (Material to Avoid): Keep away from any organic material (alcohols, acetone, etc.) and most metals as rapid decomposition may occur.
Hazardous Polymerization: Will not occur

6 - HEALTH HAZARD DATA

Routes of Entry:
Skin: Causes chemical burns.
Eyes: Causes severe eye damage.
Inhalation: May cause irritation, including a burning taste, sneezing, coughing, and difficulty in breathing.
Ingestion: Causes chemical burns of the mouth, throat and stomach.
Carcinogenicity - NTP: No
IARC Monographs: No
OSHA Regulated Carcinogen: No

7 - EMERGENCY FIRST AID PROCEDURES

Skin: Immediately flush skin with plenty of cool running water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse.
Eyes: Immediately flush with plenty of cool running water. Remove contact lenses. Continue flushing for at least 15 minutes, holding the eyelids apart to ensure rinsing of the entire eye.
Inhalation: Remove to fresh air. If irritation persists, seek medical attention.
Ingestion: Rinse mouth at once; then drink 1 or 2 glasses of water or milk. Do not induce vomiting. Never give anything by mouth to an unconscious person.

8 - PRECAUTIONS FOR SAFE HANDLING & USE

Steps to be taken in case material is released or spilled: Absorb spills with inert material and transfer to suitable container for disposal.
Waste Disposal Method: Container must be triple rinsed and disposed of in accordance with federal, state and/or local regulations. Used solution should be disposed of in accordance with federal, state and/or local regulations. Unused product is considered a hazardous waste according to RCRA criteria.
Precautions to be taken in handling and storing: Do not freeze or expose to direct sunlight. Store in a cool, well-ventilated area. Store in upright position to prevent leakage from vented caps.
Other Precautions: Keep out of reach of children. Do not ingest. Avoid skin and eye contact. Avoid contamination from any source. Never tamper with vent cap.

9 - CONTROL MEASURES

Respiratory Protection: Use in a well-ventilated area. Avoid breathing mists or vapors of this product.
VENTILATION:
Local Exhaust: Adequate ventilation to maintain recommended exposure limit
Mechanical (General): Should be sufficient
Protective Gloves: Rubber gloves, protective cuff or gauntlet type preferred
Eye Protection: Use chemical splash goggles. For continued or severe exposure, wear a face shield over the goggles.
Work/Hygiene Practices: Prompt rinsing of hands after contact. Handle in accordance with good personal hygiene and safety practices. These practices include avoiding unnecessary exposure.

10 - TRANSPORTATION INFORMATION

Regulated: DOT, IATA, IMO
Proper Shipping Name: Hydrogen peroxide and peroxyacetic acid mixtures, stabilized
Hazard Class: 5.1
Identification Number: UN3149
Packing Group: II
Label: Oxidizer, Corrosive

11 - SPECIAL INFORMATION

HMIS (Hazardous Material Identification System) Rating:
H3 F0 R1
[HMIS Hazard Index: 4 - Severe Hazard; 3 - Serious Hazard;
2 - Moderate Hazard; 1 - Slight Hazard; 0 - Minimum Hazard]

Note: This MSDS was prepared in accordance with the requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200) and is to be used only for this product. The information contained in this MSDS is, to the best of our knowledge, believed to be accurate.

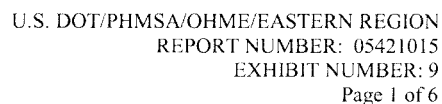
U.S. DOT/PHMSA/OHME/EASTERN
REPORT # 05421016
EXHIBIT # 8
PAGE 1 OF 1

LOCATION
Alden Medical, LLC.

PHOTOGRAPH DATE
March 15, 2005

CITY, STATE
West Springfield, MA

PHOTOGRAPHER
Chris Michalski



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

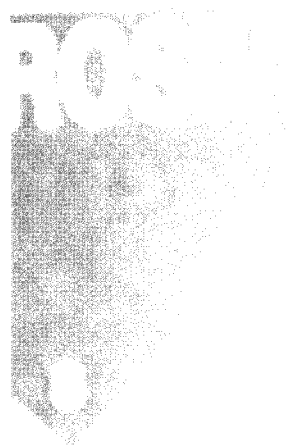
March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



HAIZER

MAR 15 2005



**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

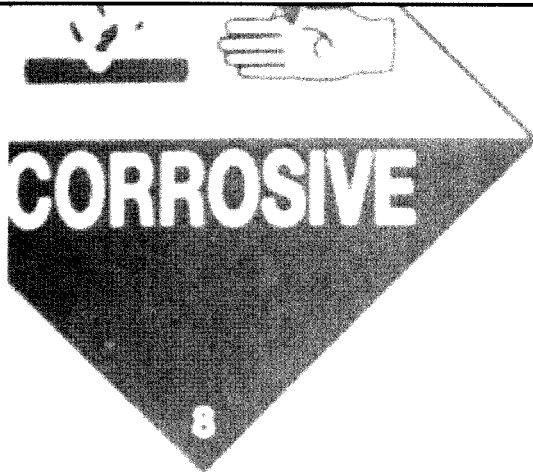
March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



Contains: Two (2) 2.5 gallon bottles
(containing 2000 ml. each)

HDC Medical, Inc.
2000 Worcester Street, Suite 200
West Springfield, MA 01103

"the **Petroleum** people"

MAR 15 2005

**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement
Photograph Summary**

LOCATION

Alden Medical, LLC.

PHOTOGRAPH DATE

March 15, 2005

CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



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Chris Michalski



**U.S. Department of Transportation
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CITY, STATE

West Springfield, MA

PHOTOGRAPHER

Chris Michalski



U.N. Approved Laboratory +AV

Certification #1584

Packaging
Design
Testing

Packaging Design And Testing
Corporation Of New England
10 Hazelwood Road
East Granby, Conn. 06026

Tested by: Engineer Thomas Frechette 1/28/03

Certification valid until 1/28/05

☐ Qualification Testing ☒ Recertification Testing

Test Requested By:

Company: ALDEN, A DIVISION OF MRC
Street Address: 360 COLD SPRING AVENUE
City and State: WEST SPRINGFIELD, MA 01089
Individual's Name: DAMON D'AMICO

Hazardous Material Classification (s) 5.1

Solid ☐ Liquid ☒ Gas ☐

Type Of Package:

Combination ☒ Single ☐ Composite ☐ L.B.C. ☐

Description of Design of Package: A SW CORRUGATION, Z SHAPED, CREATING TWO COMPARTMENTS, IS PUT INTO THE 4G BOX. A 2.5 GALLON CONTAINER, WITH ONLY A SMALL AMOUNT OF PRODUCT, WITH VENTED CAP, IS PUT INTO EACH COMPARTMENT. BOX IS STITCHED CLOSED PER BOX CLOSURE SHEET. NOTE: BOX MUST BE SHIPPED WITH VENTED CAPS UPWARDS..

Testing to Packing Group II

Test	Specification	Results
Drop	<u>5</u> Drops @ 3.9'	<u>Passed</u>
Stacking	<u>105</u> Lbs. for 24 Hrs.	<u>Passed</u>
Vibration	<u>210</u> CPM for one hour.	<u>Passed</u>
Cobb 1800-ISO 535	<u>120</u> Avg. g/m 2	<u>Passed</u>

Results Of Package Tested: Passed ☒ Failed ☐

Package Marking:

u 4GW/Y7/S/ Last two digits year box manufactured.
n USA/+AV1584

NOTE: APPROVAL # CA 0010008 FROM THE D.O.T. IS ATTACHED, ALLOWING TESTING AND SHIPPING OF THIS PACKAGE WITH 2 LITERS OF PRODUCT MAXIMUM IN THE 2.5 GALLON CONTAINERS. BECAUSE OF THIS EXCEPTION, PACKAGE MUST BE MARKED 4GW/Y7/S/LAST TWO DIGITS OF YEAR BOX MANUFACTURED.

Certified Test Report

Thomas Frechette

Page 1 of 4

U.S. DOT/PHMSA/OHME/EASTERN
REPORT # 05421016
EXHIBIT # 10
PAGE 1 OF 4

☐ If box at left is checked, the inner package meets specifications for air transport and the underlined part of this statement should be printed on the package below the UN marking. Packages tested are representative as to product as it would be packaged for shipment. Package tested is in accordance with the appropriate provisions of Chapter 9. Certification contingent upon shipper following particular packaging requirements or exceptions where applicable per publication - 49CFR,(INCORPORATING HM181) ICAO,IMDG AS PROPOSED PER RSPA.

Responsibility Disclosure: Usage of the marking of this certification mandates that it is to be used for the described package only. Validity of the certification is good only up to the recertification date, as noted on page one of this document. Certified party understands that use of the marking for any variations, without further testing by PDT, as allowed under 49CFR-178.601, will be at the complete responsibility of the shipper, eliminating Packaging Design And Testing Corporation Of New England from any liability. Any changes of suppliers, or any part of the package as identified as the certified pack, will also render this certification invalid.

Remarks:

CONDITIONING:

PACKAGE WAS PRE-CONDITIONED AT -18 DEGREES C AS PER 49 CFR 178.602.

REFERENCE PAGE 2 - DROP TEST - METHOD USED ELECTRO
MAGNET. TESTED AS PER 49CFR 178.603, BUT WITH FILL CAPACITY OF TWO
LITERS MAX. PER CONTAINER. SEE CA0010008.

REFERENCE PAGE 2 - STACKING TEST - METHOD USED - DEAD WEIGHT - BASED
ON A HEIGHT OF (3) METERS OF PACKAGES STACKED, INCLUDING SAMPLE
TESTED, AS PER 49CFR 178.606. (3) SAMPLES TESTED.

REFERENCE PAGE 2 - VIBRATION TEST - METHOD USED - THREE SAMPLES ARE
PLACED ON A LAB CORPORATION VIBRATOR AND VIBRATED FOR ONE HOUR.
TESTED AS PER 49CFR 178.608.

REFERENCE PAGE 2 - COBB TEST - (5) FIVE SAMPLES

1. 118 2. 121 3. 119 4. 119 5. 121

NOTE 1: REFERENCE PAGE 2 - PACKAGE MARKING.

UN LOGO PART OF MARKING SHOULD BE CIRCLED AND PRINTED IN LOWER
CASE LETTERS WHEN MAKING PRINTING DIES OR STENCILS FOR MARKING
PACKAGE. THE LAST TWO DIGITS OF LINE ONE REPRESENTS THE YEAR THE
CONTAINER WAS MANUFACTURED.

NOTE 2: PLEASE EXAMINE THIS REPORT UPON RECEIPT AND REPORT TO PDT
ANY DISCREPANCIES IN YOUR PRODUCT IDENTIFICATION OR PACKAGING.

 X RANDOM PRODUCTION RUN SAMPLES WERE TESTED. CERTIFICATION IS
NOT VALID UNLESS RANDOM PRODUCTION RUN SAMPLES WERE TESTED.

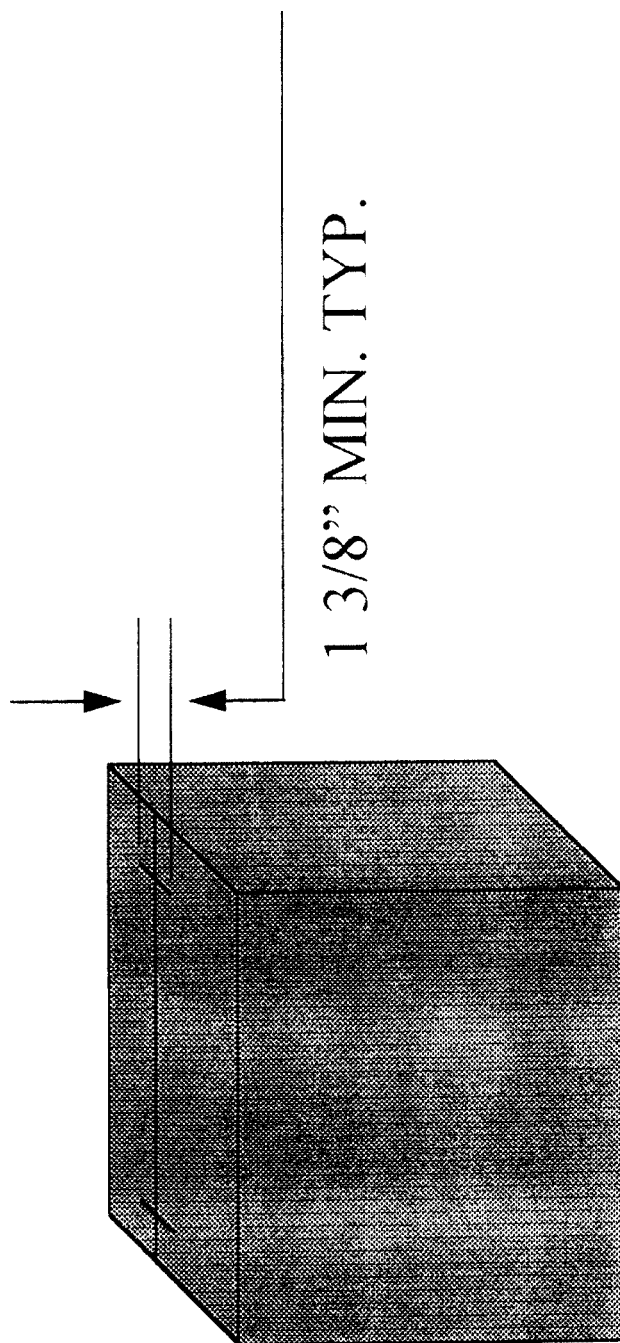
NOTE 4: TESTED PACKAGE MARKINGS, (u) 4GW/Y7/S/01
(n) USA/+AV1584

NOTE 5: PACKAGE SHOULD BE MARKED PER PAGE ONE OF THIS
CERTIFICATION WHEN RE-MANUFACTURED.

OUTER CONTAINER TYPE: 4G RSC CORRUGATED BOX.
OUTER CONTAINER MATERIAL: 275C, KW 69/26/69, GLUED.
OUTER CONTAINER DIMENSIONS: 14.75" X 10.00" X 15.25" O.D.
CONTAINER MANUFACTURER: COMMONWEALTH PACKAGING CORP., CHICOPEE, MA.
INNER CONTAINER TYPE: PLASTIC BOTTLE MANUFACTURED BY POLYCON INDUSTRIES, INC. CHICAGO, IL.
INNER CONTAINER MATERIAL: HDPE 2.5 GALLON - I.D. #2576.
CAP/COVER MATERIAL: HDPE - VENTED. I.D. #2509
CAP/COVER MANUFACTURER: PERFORMANCE SYSTEMATRIX, CALEDONIA, MI
OPENING SIZE: (1.25")
MAXIMUM CAPACITY: 2.73 GAL.
WEIGHT OF CONTAINER, EMPTY: 330 gr.
METHOD OF MANUFACTURE: BLOW MOLDED
SPECIFIC GRAVITY: 1.133
VISCOSITY: EQUAL TO WATER
ACTUAL MATERIAL TESTED: WATER/ANTIFREEZE.
WEIGHT OF TESTED PACKAGE: 13.25 LBS.
MAXIMUM GROSS WEIGHT OF SHIPABLE PRODUCT: 15.50 LBS.
NOTE: THE AMOUNT OF MATERIAL SHIPPED IS TO BE 2 LITERS MAXIMUM, TO OBTAIN THE 15.50 LB. APPROVAL WGT.

BOX CLOSURE SHEET

TWO STAPLE CLOSURE - TOP AND BOTTOM, LOCATED
APPROXIMATELY AS SHOWN.





U.S. Department
of Transportation

Research and
Special Programs
Administration

400 Seventh St., S.W.
Washington, D.C. 20590

U.S. Department of Transportation: A current copy of this approval must be maintained at each facility where such shipments are offered for transportation under the terms of this approval.

APPROVAL CA-0010008

ISSUED BY THE COMPETENT AUTHORITY OF THE UNITED STATES

1. **APPROVAL HOLDER:** Alden, a Division of Metrex Research Corp., West Springfield, MA is authorized to use this approval. Failure to comply may result in termination of this approval.
2. **REGULATORY AUTHORITY:** 49 CFR 178.601(h) - Testing using methods other than those specified in subpart M.
3. **SYNOPSIS:** Alden is authorized to perform the required performance oriented packaging tests using packagings that are filled to less than 98% capacity. The inner plastic bottles may not be shipped with more than two liters of lading.
4. **BASIS:** This approval is issued in response to a request from Alden dated August 31, 2000.
5. **PERIOD OF VALIDITY AND CONDITIONS OF APPROVAL:** This approval does not provide relief from any requirements of the Hazardous Materials Regulations except as stated herein. This approval shall remain valid until terminated by the Associate Administrator for Hazardous Materials Safety.
 - a. **Applicability and Packaging:** This approval applies to a combination package consisting of a UN 4G fiberboard box with two, 2 1/2 gallon plastic bottles, each of which will be used to ship 2 liters of peroxyacetic acid solution (35%).
 - b. **Testing:** All tests may be conducted in accordance with 49 CFR Subpart M of Part 178 by using 2 liters of the liquid in the 2 1/2 gallon containers instead of filling the inner containers to the 98% capacity as required by the Hazardous Materials Regulations.
 - c. **Marking:** The packagings must be marked UN 4GW in accordance with 49 CFR 178.503(a)(2) and must be marked with a maximum gross weight not to exceed that of the weight used during testing.

6. **SPECIAL PROVISIONS:** A current copy of this approval must be maintained at each facility from which shipments are offered for transportation under the terms of this approval.
7. **GENERAL PROVISIONS:**
- a. Failure by any person to comply with the terms and conditions of this approval and the Hazardous Materials Regulations, 49 CFR Parts 171-180, may result in the modification, suspension or termination of that person's authority to use this approval. Failure to comply may also subject that person to penalties prescribed by 49 U.S.C. §§ 5123 and 5124. This approval may be modified, suspended or terminated in its entirety if that action is justified in light of changes in circumstances or additional information not available when this approval was issued. Unless immediate modification, suspension or termination is necessary to avoid a risk of significant harm to persons or property, before action is taken, that person will be notified and provided with an opportunity to show why the proposed action should not be taken.
- b. Each "Hazmat employee", as defined in 49 CFR § 171.8, who performs a function subject to this approval must be provided training on the requirements and conditions of this approval in addition to the training required by 49 CFR §§ 172.700 through 172.704.

Issued in Washington, D.C.

Christine E. Whitney
Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety

OCT 17 2000

(DATE)

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590. Attention DHM-32

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05 APR -4 AM 11:39

March 29, 2005

Mr. Christopher Michalski
Senior Hazardous Materials Enforcement Specialist
Office of Hazardous Materials Enforcement
Eastern Region
820 Bear Tavern Road
Suite 306
West Trenton, NJ 08628

RE: Inspection

Mr. Michalski:

The purpose of this letter is to provide responses and corrective actions to the Exit Briefing document issued to Alden Medical LLC on March 17, 2005.

Probable Violation # 1

Packages must be closed in accordance with the manufacturer's closure instructions.

Response

The package will be closed in accordance with the manufacturer's closure instructions on all future production runs. Specifically, staples will be replaced with tape.

Probable Violation # 2

The letter W must appear in the UN Certification of packaging tested under a special approval. Gross mass must not exceed the one shown on the certification.

Response

The package in question will have a label applied with the correct UN Certification on all existing inventory. Changes to the artwork have been initiated with the corrugated manufacturer so that the UN Certification will be correctly stated on all future packages.

Gross mass will not exceed the one shown on the certification.

Probable Violation # 3

Shippers of placardable quantities of hazardous materials are required to register.

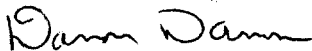
Response

Alden Medical sent in the application and required registration fee.

Alden Medical LLC opened for business on June 1, 2004. The primary mission of the Company is to provide high quality sterilents and disinfectants for infection control in the dialysis and hospital markets. Alden Medical is a small business that employs 17 people.

It is Alden Medical's intent to take what ever measures necessary to maintain compliance with DOT regulations. Since your visit, Alden has provided more in depth security training to all employees.

Cordially,



Damon D'Amico
President

Michalski, Chris <PHMSA>

From: Michalski, Chris <PHMSA>
Sent: Wednesday, April 20, 2005 1:02 PM
To: 'damon.damico@comcast.net'
Subject: Corrective action

Dear Mr. D'Amico,

I was trying to contact you regarding your response to my inspection and I was told that you were on vacation. Please note that the response letter you sent me did not include any documentation of corrective action, as discussed during my inspection. You can fax or send such documentation when you return, if you wish for me to include it with my report. Thank you.

Chris Michalski

4/21/2005

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DOT/RSPA/OHMS/OHME
EASTERN REGION

05 APR 27 AM 8:52

April 26, 2005

To: Christopher Michalski

From: Damon D'Amico, Alden DD

Date: April 26, 2005

Re: Supporting Documentation

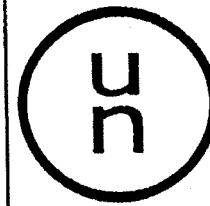
Enclosed please find a sample of the over sticker applied to current inventory reflecting the correct marking with an exception. New boxes have been ordered and will be implemented with the next production run.

I am also enclosing a copy of Alden's registration for hazardous materials.

Please include these documents with your report to demonstrate Alden's full compliance.

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Alden Medical LLC
360 Cold Spring Avenue • West Springfield, Massachusetts 01089
Phone: (413) 747-9717 • Fax: (413) 747-9721



4GW/Y7/S/01
USA/+AV 1584

U.S.DOT/PHMSA/OHME/EASTERN REGION
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UNITED STATES OF AMERICA
DEPARTMENT OF TRANSPORTATION
PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION



HAZARDOUS MATERIALS
CERTIFICATE OF REGISTRATION
FOR REGISTRATION YEAR(S) 2004-2006

Registrant: ALOE N MEDICAL LLC
DAMON DAMICO
360 COLD SPRING AVE
WEST SPRINGFIELD, MA 01089

This certifies that the registrant is registered with the U.S. Department of Transportation as required by 49 CFR Part 107, Subpart G.

This certificate is issued under the authority of 49 U.S.C. 5108. It is unlawful to alter or falsify this document.

Reg. No: 040505 001 006MN

Issued: 04/05/05 Expires: 06/30/06

Record Keeping Requirements for the Registration Program

The following must be maintained at the principal place of business for a period of three years from the date of issuance of this Certificate of Registration:

- (1) A copy of the registration statement filed with PHMSA; and
- (2) This Certificate of Registration

Each person subject to the registration requirement must furnish that person's Certificate of Registration (or a copy) and all other records and information pertaining to the information contained in the registration statement to an authorized representative or special agent of the U. S. Department of Transportation upon request.

Each motor carrier (private or for-hire) and each vessel operator subject to the registration requirement must keep a copy of the current Certificate of Registration or another document bearing the registration number identified as the "U.S. DOT Hazmat Reg. No." in each truck and truck tractor or vessel (trailers and semi-trailers not included) used to transport hazardous materials subject to the registration requirement. The Certificate of Registration or document bearing the registration number must be made available, upon request, to enforcement personnel.

For information, contact the Hazardous Materials Registration Manager, DHM-60 Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590, telephone (202) 366-4109.

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Facsimile Transmission Cover Sheet

Company

Contact

Name: U.S. Department of Transportation Person: Christopher MichalskiFax #: 1-800-989-2277Date of Fax: 4/28/05From: Darren D'AmicoThere are 2 pages in this transmission (including cover sheet)

Statement of Confidentiality: The documents accompanying this facsimile transmission contain information from this office, which is confidential and/or legally privileged. The information is intended only for the use of the individual or entity named on this transmission sheet. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this information is strictly prohibited and that the documents should be returned to this company immediately. If you received this transmission in error, please notify this office by telephone so that we can arrange for the return/disposal of the documents to us at no cost to you.

**IF YOU HAVE PROBLEMS WITH THIS TRANSMISSION,
PLEASE CALL: (413) 747-9717**

Comments:

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Alden Medical LLC
360 Cold Spring Avenue • West Springfield, Massachusetts 01089
Phone: (413) 747-9717 • Fax: (413) 747-9721



In-Depth Security Training Record

On March 29, 2005, In-Depth Security Training was administered by
Damon D'Amico
360 Cold Spring Avenue
West Springfield MA 01089

The following employees received this training

Asselin, Shirley
Banas, Carl
Corridan, Chris
Eynullayeva, Tunzala
Fredette, Daniel
Navarro, Carmen
Parks, John
Rakhubenko, Ruvim
Rinaldi, David
Roj, Jillian
Sanchez, Daniel
Stevens, Kimberly
Subira, Greg
Yurashko, Mikhail

The training materials consisted of the Alden Facility Security Plan.

I hereby certify that the employees listed above received In-Depth Security Training

Damon D'Amico
President of Alden Medical LLC

3/31/05
Date

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